



STATE OF WASHINGTON
WASHINGTON STATE BOARD OF HEALTH
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December 10, 2002

TO: Washington State Board of Health Members
FROM: Vickie Ybarra, WSBOH Member
RE: **CHAPTER 246-680 WAC- PRENATAL TESTS—CONGENITAL AND HERITABLE DISORDERS**

Background and Summary

At today's State Board of Health meeting we will hold a public hearing on the proposed revisions to Chapter 246-680 WAC-Prenatal Tests—Congenital and Heritable Disorders.

The Board has worked in conjunction with DOH to conduct an extensive analysis and a thorough public review process over the past 18 months. After the public hearing today I will ask that the Board to consider adopting the revised WAC based on public review, extensive analysis, and final public testimony. The proposed WAC and the economic analysis are included in Tab 13.

Chapter 246-680 WAC establishes rules pertaining to State Board of Health standards for screening and diagnostic procedures for prenatal diagnosis of congenital disorders of the fetus. The WAC also establishes Department of Health criteria and timelines regarding the availability and use of prenatal tests for health care providers to share with pregnant women and couples. The specific goal of the Prenatal Tests WAC is to assure that pregnant women have accurate information about prenatal testing procedures and will be able to choose whether or not to undergo prenatal screening or testing to determine the health of their unborn baby.

The Board has the statutory authority to set standards for screening and diagnostic procedures for prenatal diagnosis of congenital disorders of the fetus based on RCW 48.21.244, 48.44.344, and 48.46.375. These three statutes require group disability contracts, group health services contracts and group health maintenance agreements that cover pregnancy related services and offer benefits for prenatal diagnosis of congenital disorders in accordance with standards prescribed by the State Board of Health. The Prenatal Tests WAC is also based on RCW 70.54.220 that requires all licensed and certified prenatal health care providers to inform their pregnant clients about the availability of prenatal tests within time limits prescribed by the Department of Health.

The proposed revised WAC updates the styles of rules, deletes obsolete rules, updates the scope of prenatal genetics testing required for health insurance packages and adds three new tests: Maternal Hepatitis B, Group B Strep, and Fluorescent in-situ hybridization (FISH). These changes are needed because (a) the WAC has not been updated in the last 10 years and standards of care in prenatal diagnosis and screening have evolved in that timeframe; (b) it does not reflect statutory requirements because not all prenatal tests in the WAC include time periods within which they need to be made available to pregnant women; and (c) it needs improvements in readability and consistency with current standards of practice. The economic analysis indicates that the benefits of the WAC revisions will outweigh any costs.

The rule revision process has involved many interested parties including, medical experts, providers, consumer groups and individuals, public and private third party payers, the State Genetics Advisory Committee, and State Perinatal Advisory Committee, and state agencies. Input during the rule revision process was primarily from medical experts and providers. Drafts of the WAC revisions were shared on multiple occasions with both public and private third party payers and no concerns were raised.

Board Action Recommended

I would like the Board to consider for adoption the changes to Chapter 246-680 WAC-Prenatal Tests-Congenital and Heritable Disorders as proposed.